K070287

510(k) Summary of Safety and Effectiveness

Submitter
Photonic Optische Geräte GesmbH & CoKG
Seeböckgasse 59
A-1160 Vienna, Austria
Mr. Dieter Feger (GM)
phone: +43(1)4865691-0
prepared: 13th March 2006

Device Submitted
Xenon/Metal halide light source with fiber and headlight

Proprietary Name
PS series

Common Name
Light source

Predicate Devices

Applicant	Predicate Device	510(k)	class, code, 21CFR
Cogent/WelchAllyn	Solartec Source ST270 (CL300)	K983714	II, FFS, 876.1500
Cogent/WelchAllyn	Micro Link endoscopic fiber cable	K001698	II, FFS&KOD 876.1500 II, HBI&FST, 878.4580
Isolux America	1300 XSBP	K022384	II, HET, 884.1720
Isolux America	1125 XSB	K052979	II, HBI, 878.4580 I, EAZ, 872.4630
Isolux America	Fiber optic surgical headlight	K991572	II, FST, 878.4580
Isolux America	fiberoptic cable	K991208	II, HBI, 878.4580

Device Description
The cold light sources of the PS series consist of short arc metal-halide or xenon lamps, driven by electronic ballasts. Optical components such as mirrors, lenses, filters and coatings focus the light to a very small diameter of typically 1.5-3mm. Fiber light guides (single or bundles) transmit the light to the application such as headlights, endoscopes or other lighted tools.

Intended Use
The AC-powered dental operating light, which can be attached via optical fibers to a headlight, is a device intended to illuminate oral structures and operating areas. The device is intended for Prescription Use only!

Technological Characteristics Similarities
The light sources PS series with fibers and headlights are similar in use, design and function to those from Isolux and Cogent (WelchAllyn).

Performance Data
No performance data is required for this Class I device nor requested by FDA (ODE).

Safety

The device is designed for and fully meets following international safety standards:

- IEC 60601-1:1988 +A1:1991 +A2:1995
- IEC 60601-1-2:2001
- IEC 60601-2-18:1996 +A1:2000
- UL2601-1:1997
- CAN/CSA-C22.2 No. 601-1-M90
- 47 CFR Ch.1 Part 15 (FCC)
- IEC 60601-2-41:2000 (in accordance to UV measurements)

Effectiveness

Metal halide or xenon arc lamps produce white light similar to sunlight. All light transmitting elements such as mirrors, lenses, filters and coatings are determined not to change the color temperature of the system.

This device uses an extra short arc lamp, which improves the effectiveness of focusing the light with the help of optics into a small fiber (single or bundle) with diameters typically between 1-3mm. Other commercial equipment uses fiber bundles with diameter of typically 4-6mm to transmit the same light flux.

Conclusion

The technological differences to the predicate devices do not affect the safety or efficacy of the sumbitted devices, therefore leads to the conclusion, that the cold light series PS including fibers and headlights are substantial equivalent to the Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Photonic Optische Geräte GmbH & CoKG
C/O Mr. Stefan Preiss
Responsible Third Party Official
TÜV SÜD America, Incorporated
1775 Old Hywy 8 NW
New Brighton, Minnesota 55112-1891

FEB 12 2007

Re: K070287
Trade/Device Name: PS Series with Fiber Light Guide and Headlight
Regulation Number: 872.4630
Regulation Name: Dental Operating Light
Regulatory Class: I
Product Code: EBA, EAZ, EAY
Dated: January 23, 2007
Received: January 29, 2007

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

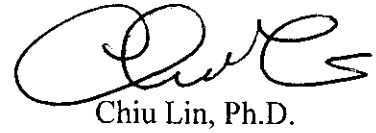
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: PS series with fiber light guide and headlight

Indications For Use:

The AC-powered dental operating light, which can be attached via optical fibers to a surgical headlight, is a device intended to illuminate oral structures and operating areas.

Prescription Use: **YES** AND/OR Over-The-Counter Use: **NO**
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

K070287